

**Appl. No.** : **09/996,030**  
**Filed** : **November 16, 2001**

### **REMARKS**

Claims 2, 3, 5-8, and 15-21 have been cancelled. Claims 1, 10, 12, and 13 have been amended. Claims 1, 4, 9-14, and 22 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### **Information Disclosure Statement**

Applicants gratefully acknowledge the Examiner's indication that the Information Disclosure Statements of 11/6/01, 2/28/02, 6/20/02, and 7/23/03 have been considered.

Regarding the 6-205695 reference submitted with the Information Disclosure Statement of 2/2/04, the Examiner states that this submission fails to comply with 37 C.F.R. § 1.98 (a)(3) because a statement of relevancy for this reference was not provided. However, Applicants listed and provided an English translation of an Office Action from the Japanese Patent Office on the Information Disclosure Statement of 2/2/04 which stated that 205695/1994 discloses a population of basophils (see page 1/2 of the Office Action from the Japanese Patent Office labeled "Notification of Reason for Rejection"). Applicants note also that there is no art rejection based upon this reference in the Office Action from the Japanese Patent Office.

As set forth in M.P.E.P. 609 III.A.A(3) "the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office" (emphasis added). In view of Applicants' submission of the Office Action from the Japanese Patent Office which referred to the 6-205696 reference, Applicants respectfully submit that they have met the requirements of 37 C.F.R. § 1.98 (a) (3). However, as an added measure, Applicants will also forward an English translation of this reference in a separate paper shortly.

#### **Rejections under 35 U.S.C. § 112, second paragraph**

Claims 8 and 12 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This ground of rejection is moot with respect to claim 8 which has been canceled.

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Claim 12 has been amended as kindly suggested by the Examiner.

In view of Applicants' amendment and cancellation of claim 8, this ground of rejection may be properly withdrawn.

Claims 1, 8-9, and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

Without acquiescing to the rejection, Applicants have amended claim 1 to include the limitations of claim 2. As claim 2 was not subject to this ground of rejection, Applicants believe that this amendment overcomes the rejection.

Claim 8 has been canceled.

Claims 9 and 22 depend from claim 1 and include the limitations thereof.

In view of Applicants' amendments, withdrawal of the above ground of rejection is respectfully requested.

#### **Double patenting**

I. Claims 1, 2, 4, 10-12, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,323,321 in view of Hermine, et al. and further in view of Shionigi & Co.

II. Claims 8-9 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,323,321 in view of Hermine, et al. and further in view of Shionigi & Co and Irsch, et al.

Without acquiescing to the rejection and in order to expedite prosecution, the above grounds of rejection are traversed by submission of a terminal disclaimer.

In view of Applicants' terminal disclaimer, submitted herewith, withdrawal of the above ground of rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 102(e)**

Claims 1, 2, 4, 10-12 and 22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Buhning (U.S. Patent No. 6,323,321) as evidenced by Blom, et al. (European Journal of

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Immunology, 1992, vol. 22, no. 8, pages 2025-2032) and Hermine, et al. (Blood, 1992, Vol. 80, No. 12, pages 3060-3069).

This ground of rejection is believed to be overcome by Applicants amendment of claim 1 to delete "precursor cells of basophils, and precursor cells of mast cells." This amendment is responsive in particular to the Examiner's comments on page 12 of the Office Action.

UT-7 and KU812 are both non-differentiated leukemia cell lines. These cell lines do not include mast and/or basophil cells.

Like any non-differentiated cell line, these leukemia cell lines can differentiate into a cell having mast cell and basophil cell features by addition of appropriate growth factors. These cells, differentiated from either UT-7 or KU812 leukemia cell lines, may not have all of the identifying features of basophil or mast cells. At best, UT-7 and KU812 may be considered to be precursors of basophil or mast cells, respectively. In order to expedite prosecution, Applicants have canceled "precursor cell of basophils, and precursor cells of mast cells" from claim 1. As UT-7 and KU812 cells do not include mast or basophil cells, but, at best, only precursors of such cells, the claims as amended cannot be anticipated by Buhring.

Applicants believe that the present amendment clearly distinguishes Applicants' claimed subject matter from the teachings of the prior art. In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 8-9 and 13-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Buhring (U.S. Patent No. 6,323,321) in view of Irsch, et al. (WO 97/ 46880).

As discussed above, Buhring does not teach or suggest the binding of 97A6 to basophil or mast cells. Both UT-7 and KU812 cell lines are cancer cell lines that do not have characteristics of basophil or mast cell lines in the absence of inducers such as serum starvation. Accordingly, there was no motivation in Buhring to use the 97A6 antibody for the binding of either mast cells or basophil cells and no reasonable expectation of success. To the extent that UT-7 or KU812 cells lines might be deemed precursors of basophil or mast cells, this subject matter has been canceled from claim 1. The cited references do not teach or suggest the invention as now claimed.

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In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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